JUL 1 0 2000

K001214

510(K) SUMMARY

Submitted by:

Michael E. Pfleger
Director, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 551-4877 (Phone)
(817) 551-4630 (Fax)

Device Name:

Common Name: Contact Lens Care Multi-Purpose Disinfecting Solution

Proprietary Name: OPTI-FREE® *EXPRESS*® Multi-Purpose Disinfecting Solution

Indications for Use:

For use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution can also be used as a diluent for OPTI-FREE® SUPRACLENS® Daily Protein Remover or OPTI-ZYME® Enzymatic Cleaner.

Description:

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution is a sterile, buffered, isotonic, aqueous solution containing sodium citrate, sodium chloride, boric acid, sorbitol, AMP-95, TETRONIC® 1304, with edetate disodium 0.05%, POLYQUAD® (polyquaternium-1) 0.001% and ALDOX™ (myristamidopropyl dimethylamine) 0.0005% as preservatives.

Substantial Equivalence:

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution is substantially equivalent, in terms of its actions and indications for use, to OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution cleared for marketing under 510(k) K973332, originally submitted as P830034/S32, K974624 and K983780. OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution meets the guidelines set forth in FDA's May 1, 1997 Guidance for Industry; Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

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Safety and Effectiveness:

Cleaning Studies

Laboratory studies were conducted with OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution. The performance characteristics evaluated were cleaning efficacy, passive cleaning and protein build up with Group I and Group IV soft contact lenses and its ability to clean laboratory deposited lenses. These laboratory studies demonstrated the cleaning efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution when used daily according to the modified directions for use. Studies were conducted demonstrating the contribution to lens cleanliness of the cleaning ingredients in the formulation.

Microbiology Studies

A series of studies were completed to demonstrate the microbiological efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution. These studies were previously submitted under 510(k) K973332, originally submitted as P830034/S32, K974624 and K983780. Additional microbiological studies were conducted demonstrating the efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution under the modified directions for use. All results were satisfactory.

Clinical Study

A one-month (randomized) concurrently controlled, observer-masked (investigator and chemical analyst) and patient-masked, parallel group, multi-site study was conducted to demonstrate the safety and efficacy of OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution used with and without OPTI-FREE SUPRACLENS® Daily Protein Remover. The control used in the study was Bausch & Lomb ReNu Multi-Plus® Multi-Purpose Solution. All three regimens are clinically acceptable in maintaining lens cleanliness when used according to directions as measured by residual lysozyme (HPLC) and Rudko observation on Day 30 lenses. The safety of OPTI-FREE EXPRESS Multi-Purpose Solution used with and without OPTI-FREE SUPRACLENS® Daily Protein Remover, when used according to directions for use, is clinically acceptable and similar to the Bausch & Lomb ReNu Multi-Plus® Multi-Purpose Solution regimen.

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution used with and without OPTI-FREE SUPRACLENS® Daily Protein Remover was demonstrated to be substantially equivalent to Bausch & Lomb ReNu Multi-Plus® Multi-Purpose Solution.

Biocompatibility Testing

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution meets the guidelines set forth in the Premarket Notification 510(k) Guidance Document for Contact Lens Care Products.

OPTI-FREE *EXPRESS* Multi-Purpose Disinfecting Solution remains unchanged from the previously approved product except for the labeling. The labeling changes require no new biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 0 2000

Michael E. Pfleger
Director
Regulatory Affairs
Alcon Research, LTD.
6201 South Freeway
Fort Worth, TX 76134-2099

Re: K001214

Trade Name: OPTI-FREE EXPRESS[R] Multi-Purpose Disinfecting Solution (Modified cleaning directions for lenses replaced in 30 days or less)
Regulatory Class: II
Product Code: 86 LPN
Dated: April 12, 2000
Received: April 14, 2000

Dear Mr. Pfleger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K001214

Device Name: OPTI-FREE® *EXPRESS*® Multi-Purpose Disinfecting Solution

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Myra Smith

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001214

Prescription Use_____ OR Over-The Counter Use_X_
(Per 21 CFR 801.109)